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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/621,146	07/21/2000	Chryslain Sumian	BJA 254A	3940

7590 02/11/2003

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East Longmeadow, MA 01028

EXAMINER

DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/621,146

Applicant(s)

SUMIAN, CHRYSLAIN

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 2, and 4-20 are pending in the instant application. Acknowledgement is made of Applicant's response filed 1/8/03. In view of Applicant's arguments, the finality of the previous Office Action mailed 9/24/2002 is withdrawn.

Claim Rejections - 35 USC § 112

1. Claims 1-2 and 4-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has included the limitations of the composition used "with an intact stratum corneum". This limitation were not contained in the originally filed non-provisional application (filed 7/21/00). As such, it is held to be new matter.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-2, 4-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al., further in view of Schaefer et al. (U.S. Pat. No. 5,292,512).

Suzuki teaches slow-releasing medical preparations that can be administered to wet mucous surface membrane and skin of men or animals. The preparation has an adhesive layer and a non-adhesive layer; the adhesive layer has the property of

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swelling upon moistening, and as it swells, slowly releasing the medicament contained in the preparation. A list of suitable polymers are contained in Table 1, col. 6.

Schaefer teaches the use of microspheres containing active products for topical application. The microspheres are designed such that when the spheres enter the follicles, they diffuse the active product into the follicular canal and surrounding tissues (col. 1, lines 38-53). The microspheres can be made using polymers that swell.

Schaefer teaches that topical applications do not have the desired effectiveness (for the active ingredient) because the epidermis forms a barrier. Schaefer found that if the microspheres for a composition are chosen from a particular size range, the effectiveness (of the active ingredient) is increased in a very unexpected manner.

Studies conducted have established that this improvement was linked with the entry of the microspheres into sebaceous follicles. Column 5, lines 4-11 teach massaging, column 15, lines 46-50 teach application to the scalp, and column 5, lines 19-23 teach application to the forehead.

It would have been obvious to one with ordinary skill in the art to use the microspheres of Schaefer in the preparation of Suzuki's because of the unexpected increased effectiveness of the active ingredient which arises from the use of microspheres entering into sebaceous follicles (thus providing motivation to utilize the teachings of Schaefer and Suzuki).

Response to Arguments

3. Applicant's arguments with respect to the 112, 1st paragraph rejection of the added limitation "to prevent collapse of said follicle during release of said compound/drug" is sufficient to overcome the rejection.
4. Applicant's arguments with respect of the rejection under 102(b) as being anticipated by Suzuki et al. are sufficient to overcome the rejection.
5. Regarding the 112, 1st paragraph rejection as it applies to the added limitation "with an intact stratum corneum", Applicant asserts that in the specification, nowhere is it (the stratum corneum) described as broken, so it must be intact. It is the examiner's position that whereas the stratum corneum is described throughout the specification, there is no indication that the stratum corneum is only in an intact state. Thus the rejection is maintained.
6. Applicant asserts that the examiner has applied hindsight in combining the teachings of Suzuki and Schaefer to make the instant invention obvious. The examiner reminds the Applicant that it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the level of ordinary skill in the art would have knowledge that the use of microspheres in an application would have unexpected benefits for the effectiveness of the active ingredient. Motivation to use the microspheres in an invention such as Suzuki would have arisen to increase the

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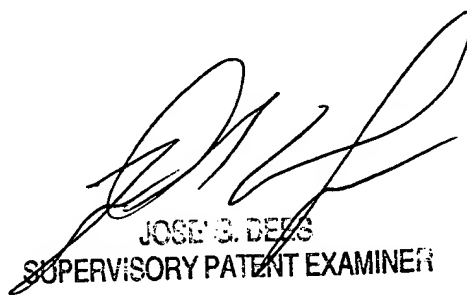
effectiveness of the active ingredient. The effectiveness of the active ingredient is increased by allowing the microspheres to enter the sebaceous follicle. The rejection is thus maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
February 7, 2003


JOSE B. DEES
SUPERVISORY PATENT EXAMINER
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